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EXAMINER	
NOAKES, SUZANNE MARIE	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
06/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/574,575	CONTI ET AL.	
	Examiner	Art Unit	
	SUZANNE M. NOAKES	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 10-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/14/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group IV, claim 9 in the reply filed on 20 April 2009 is acknowledged. The traversal is on the ground(s) that even if Kufer et al. does anticipate Group II, at the very least the structural features of Group I and III are shared with Group IV, e.g. the 3-D structural information about Aurora-A kinase, and furthermore, the subject matter of Group V is the result of performing the process of Group IV. This is not found persuasive because the special technical as stated by Applicants being shared by Groups I-V, is inherently destroyed by the findings of Kufer et al., e.g. at least a molecule or molecular complex that has the ligand binding site of the Aurora-A kinase.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 14 March 2008 has been considered by the examiner. See initialed and signed PTO-1449.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The Brief Description of the Drawings describe "Figure 1E" on p. 7 of the specification, however, said drawing is not present in the submitted drawings.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Compliance with Sequence Rules

4. The sequence listing, filed in computer readable form (CRF) and paper copy on 04/04/2006, has been received and entered. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to **fully** comply with the requirements of 37 C.F.R. § 1.821 through 1.825;

Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

MPEP 2401.02 states:

> The sequence rules embrace all unbranched nucleotide sequences with ten or more bases and all unbranched, non-D amino acid sequences with four or more amino acids, provided that there are at least 4 "specifically defined" nucleotides or amino acids. The rules apply to all sequences in a given application, whether claimed or not.

The following Figures contain sequences that contain four or more consecutive amino acids without any corresponding SEQ ID NO: and/or no reference to any SEQ ID NO: in the Brief Description of the Drawings.

a) Figure 2D shows an alignment of TPX2 N-terminal domain from several species without any corresponding sequence identifiers.

b) Figure 2E shows an alignment of Aurora-A catalytic domain from three different species without any corresponding sequence identifiers.

c) In the instant case, each .pdb file listed as Figures 5 and 6, specifically define more than four amino acids in a specific sequential order and thus each Table must identify the sequence disclosed therein. Including the appropriate SEQ ID NO: in the Table heading is sufficient for identification purposes.

* If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or

1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

Claim Objections

5. Claim 9 is objected to because of the following informalities: said claim is dependent upon a withdrawn claim. Said claim 9 should be rewritten in independent form to include all the limitations of the withdrawn claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claim 9 is rejected under 35 U.S.C. 102(**a & e**) as being anticipated by Anderson et al. (WO 03/031606 A2 - cited on IDS).

The claim is drawn to a method of identifying a compound that modulates the activity of Aurora-A kinase activity by using *any* combination of steps recited as: a) modeling test compounds that fit spatially into the Aurora-A binding site as defined by structure coordinates according to Table B; b) using said structure coordinates or binding site as set forth in claim 7 to identify structural and chemical

features; c) employing identified structural or chemical features to design or select compounds as potential Aurora-A modulators; d) employing the three-dimensional structural model or the ligand binding site to design or select compounds as potential Aurora-A modulators; e) synthesizing the potential Aurora-A modulators; f) screening the potential Aurora-A modulators in an assay characterized by binding of a test compound to the Aurora-A; and g) modifying or replacing one or more amino acids from Aurora-A selected from the group consisting of Q127, W128, R126, L159, F157, E170, L169, V206, Y199, H187, R179, L178, V182, Y199, L188, I184, V252, K250, P282, H280 of Aurora-A according to Table B.

Thus, this claim reads on any portion of said claim such as only synthesizing potential modulators of Aurora-A (part e), or using any structural coordinates from any Aurora-A structure to identify modulators etc.

Anderson et al. teach the three-dimensional structure of human Aurora-A kinase (also known as Aurora-2 kinase) catalytic domain of amino acids 122-396 [T287D] crystallized in the presence of the ATP-analogue AMP-PNP – TABLE 1 (pp. 11-43); And also the structure of human Aurora-A kinase [T287D] 122-400 crystallized in the presence of a synthetic inhibitor (formula II – see p. 8) – TABLE 2 (pp. 44-103).

They specifically teach a method of producing a modulator of Aurora-A kinase (particularly inhibitors) by identifying or designing a compound or molecule that tis into the active site pocket of the ATP binding pocket by performing *in silico*/rationale drug design by using the 3-D structures of Tables 1 and 2 (see p. 110, 1st paragraph; p, 112 line 15 - p. 113, line 12; p. 114, line 23-32 and claims 8, 9, 11, 13-15).

Thus, since the claim is limited to combining any steps from a-g (which is not inclusive of all of the steps and minimally only one step need be employed) then this teaching anticipates the instant claim, for instance any of steps c, d, e, f and/or g.

8. Claim 9 is rejected under 35 U.S.C. 102(e) as being anticipated by Cheetham (US 7,361,492 - which has a priority date of 05/01/02).

The claim is as drawn above. Cheetham et al. teach the crystallization/crystal structure of Aurora-A kinase (also known as Aurora-2 kinase) catalytic domain (amino acids 127-390) in complex with four different inhibitors – see summary of Tables 1-4 and claim 1 and Figures 1-4. Cheetham et al. specifially teach using the structural coodinates of Tables 1-4 in rational drug design to find modulators of Aurora-A kinase activity (see col. 22, line 50 - col. 29, line 46; especially, col. 25, lines 12-41). The process uses many well known methods, programs and application known in the art such as those computer programs found in the CCP4 suite and those listed in col. 27-28.

Thus, since the claim is limited to combining any steps from a-g (which is not inclusive of all of the steps and minimally only one step need be employed) then this teaching anticipates the instant claim, for instance any of steps c, d, e, f and/or g.

Reference of Interest

9. US patent 7,214,518 claims priority to WO 03/031606 cited above.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZANNE M. NOAKES/
Primary Examiner, Art Unit 1656
15 June 2009